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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE SCHERING-PLOUGH CORPORATION SECURITIES LITIGATION	:	Master File No: 01-CV-0829 (KSH/MF)
	:	**Electronically Filed**
	:	**Oral Argument Requested**

LEAD PLAINTIFF'S AMENDED MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT

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Lead Plaintiff, the Florida State Board of Administration, by its undersigned attorneys, respectfully submits this memorandum of law in support of its motion pursuant to Rule 56 of the Federal Rules of Civil Procedure for partial summary judgment against defendants Thomas Kelly and Jack Wyszomierski.

I. PRELIMINARY STATEMENT

This is a certified securities class action brought on behalf of purchasers of Schering-Plough Corp. ("Schering-Plough" or the "company") stock during the period through and including May 9, 2000 to February 15, 2001 (the "Class Period"). Plaintiffs allege that during the Class Period, Schering-Plough and the individual defendants, Richard Kogan (Chairman and CEO), Raul Cesan (Director, President and COO), Jack Wyszomierski (CFO) and Thomas Kelly (Controller), knowingly, or with reckless disregard for the truth, disseminated a series of materially false and misleading statements in violation of Sections 10(b), 20(a) and 20A of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. Plaintiffs contend that defendants' statements failed to disclose severe, widespread and systemic deficiencies in Schering-Plough's manufacturing and quality operations at its facilities in New Jersey and Puerto Rico. Plaintiffs further contend that defendants' statements concerning a New Drug Application ("NDA") for an allergy medicine known as Clarinex were false and misleading because they failed to disclose that the company's ongoing manufacturing and quality

deficiencies were a significant impediment to approval of the application by the United States Food and Drug Administration ("FDA" or the "Agency").

Toward the end of the Class Period, on January 19, 2001, the FDA issued an "approvable" letter for Clarinex that effectively withheld approval of the drug as a result of the manufacturing and quality deficiencies that existed at the company's facilities in New Jersey and Puerto Rico. Shortly thereafter, on January 25, 2001, Schering-Plough issued a press release that confirmed receipt of the approvable letter, but withheld any mention of the reasons for the FDA's action. When, after the close of the market on February 15, 2001, Schering-Plough disclosed that it had been cited for manufacturing and quality deficiencies at its facilities in New Jersey and Puerto Rico and that such deficiencies would need to be resolved before the FDA would approve Clarinex, the price of the company's stock crumbled by 15 percent, from $48.32 to $41.25, resulting in enormous losses for the company's shareholders. Clarinex ultimately received FDA approval about a year later, but only as part of negotiations that led to the entry of a consent decree in May 2002 that required Schering-Plough to pay a $500 million fine, the largest ever imposed by the FDA.

The statements that form the basis of plaintiffs' claims can be roughly divided into two categories. One category is comprised of certain public filings that Schering-Plough made with the Securities and Exchange Commission ("SEC")

that contained statements discussing the regulation of the company's business by the FDA, including matters pertaining to compliance with good manufacturing practices ("GMPs"), the regulations establishing the minimum standards that govern virtually all aspects of pharmaceutical manufacturing. Specifically, the SEC filings at issue are each of Schering-Plough's quarterly reports on Form 10-Q filed during 2000 and the company's 1999 annual report on Form 10-K. Although the 1999 10-K was filed approximately two months before the beginning of the Class Period, the company's 2000 Forms 10-Q incorporated by reference language from the 1999 10-K that plaintiffs allege was false and misleading. Another category of statements on which plaintiffs' assert claims is comprised of press releases issued by Schering-Plough about the Clarinex NDA.

This limited motion for partial summary judgment concerns only Schering-Plough's SEC filings and the state of knowledge of two of the defendants -- Kelly and Wyszomierski -- in signing them. In order to prevail on their claims under Section 10(b), plaintiffs must prove, among other things, that defendants made a materially misleading statement with knowledge of its falsity or with reckless disregard of the truth. *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 535 (3d Cir. 1999). The question presented by this motion is whether corporate officers who have no knowledge of the facts pertaining to disclosures in SEC filings, and who fail to undertake any investigation of such facts, can be deemed as a matter of law

to have acted "recklessly" in signing those filings. Because the record is incontrovertible that Kelly and Wyszomierski neither knew nor investigated any of the pertinent facts concerning Schering-Plough's compliance problems and its deteriorated relationship with the FDA, plaintiffs submit that if, upon trial of this matter, the jury finds that Schering-Plough's SEC filings were materially misleading, they would then be entitled to a jury instruction directing a finding that these defendants acted in reckless disregard of the truth.

II. FACTUAL BACKGROUND

A. Schering-Plough's Misleading SEC Disclosures

Approximately two months before the beginning of the Class Period, on March 2, 2000, Schering-Plough filed with the SEC its annual report on Form 10-K for the year ended December 31, 1999. [Accompanying Declaration of Robert A. Hoffman ("Hoffman Decl."), Ex. 1]. The 1999 10-K was signed by defendants Kelly and Wyszomierski, among others. The 1999 Form 10-K included significant discussion of the FDA's regulation of Schering-Plough's business, including matters pertaining to GMP compliance.

Under the heading, "Government Regulation," the 1999 10-K stated:

> Pharmaceutical companies are subject to extensive regulation by a number of national, state and local agencies. Of particular importance is the United States Food and Drug Administration (FDA). It has jurisdiction over all the Company's businesses and administers requirements covering the testing, approval, safety, effectiveness, manufacturing, labeling and marketing of the Company's products. In

> some cases, FDA requirements and/or reviews have increased the amount of time and money necessary to develop new products and bring them to market in the United States.
>
> On an ongoing basis the FDA regulates the facilities and procedures used to manufacture pharmaceutical products in the United States or for sale in the United States. All products made in such facilities must be manufactured in accordance with "good manufacturing practices" established by the FDA. The FDA periodically inspects the Company's facilities and procedures to assure compliance.
>
> Failure to comply with government regulations can result in delays in the release of products, seizure or recall of products, suspension or revocation of the authority necessary for the production and sale of products, fines and other civil or criminal sanctions.
>
> The 1999 10-K, included among "Cautionary Factors That May Affect

Future Results," the following:

> Failure to meet "good manufacturing practices" established by governmental authorities can result in delays in the release of products, seizure or recall of products, suspension or revocation of the authority necessary for the production and sale of products, fines and other civil or criminal sanctions.
>
> Under the heading "Additional Factors Influencing Operations," the 1999

10-K represented, *inter alia*:

> The Company is subject to the jurisdiction of various national, state and local regulatory agencies and is, therefore, subject to potential administrative actions. Of particular importance is the Food and Drug Administration (FDA) in the United States. It has jurisdiction over all the Company's businesses and administers requirements covering the testing, safety, effectiveness, approval, manufacturing, labeling and marketing of the Company's products. From time to time, agencies, including the FDA, may require the Company to address various manufacturing, advertising, labeling or regulatory issues. Failure to comply with governmental regulations can result in delays in the

> release of products, seizure or recall of products, suspension or revocation of the authority necessary for the production and sale of products, fines and other civil or criminal sanctions.
>
> From time to time, the Company has received Warning Letters from the FDA pertaining to various manufacturing issues. Among these, the Company has received a Warning Letter from the FDA relating specifically to manufacturing issues identified during FDA inspections of the Company's aerosol products (albuterol and VANCERIL) manufacturing facilities in New Jersey. The Company is implementing remedial actions at these facilities. The Company has met with the FDA on several occasions to apprise the agency of the scope and status of these activities. An FDA inspection of the Company's New Jersey manufacturing facilities is ongoing. The Company cannot predict whether its remedial actions will resolve the FDA's concerns, whether the FDA will take any further action or the effect of this matter on the Company's operations.

[Hoffman Decl., Ex. 1].

During the Class Period, these disclosures were essentially repeated in respective quarterly reports on Form 10-Q that Schering-Plough filed with the SEC on May 9, 2000, August 9, 2000 and November 13, 2000. [Hoffman Decl., Exs. 2-4]. Each of the Forms 10-Q was signed by defendant Kelly. The Forms 10-Q expressly incorporated by reference Item 1 of the 1999 10-K, which included the "Government Regulation" and "Cautionary Factors" sections quoted above. The 2000 Forms 10-Q also contained a section entitled "Additional Factors Influencing Operations." This section was also identical to language contained in the 1999 10-K, except that it did not include the sentence: "An FDA inspection of the Company's New Jersey manufacturing facilities is ongoing." This statement was

demonstrably false. Schering-Plough's 1999 10-K was filed on March 2, 2000. The FDA inspection in New Jersey concluded several days earlier, on February 25, 2000, with the issuance of numerous citations of GMP violations. [Hoffman Decl., Ex. 5]. Schering-Plough never corrected this misstatement and never informed investors about the results of the inspection in its Forms 10-Q filed during the Class Period. [*See* Hoffman Decl., Exs. 2-4].

Plaintiffs allege that, taken together, Schering-Plough's SEC filings conveyed a highly misleading impression that the only ongoing compliance issues of significance to investors concerned the company's manufacture of aerosol products in New Jersey, a matter the market was already aware of as a result of several public, nationwide recalls of these products that occurred in the months preceding the Class Period. The disclosures utterly failed to convey the reality of Schering-Plough's true compliance status; including, among other things, that there were severe, widespread and systemic deficiencies in the company's manufacturing and quality operations at its facilities in Kenilworth and Union, New Jersey and Las Piedras and Manati, Puerto Rico; that such deficiencies were not limited to aerosol products, but cut across all types of dosage forms (e.g., tablets, capsules, liquids, ointments, etc.) manufactured at those facilities, including most of the company's top-selling products; and that the existing deficiencies required a comprehensive company-wide remediation effort that

included the temporary shutdown of production lines, the expenditure of hundreds of millions of dollars to upgrade plants and equipment, the hiring of hundreds of additional personnel to strengthen its quality and production areas and the implementation of major structural and organizational changes to address quality issues throughout the company.

The discovery in this matter documents the widespread and systemic manufacturing and quality deficiencies that existed at Schering-Plough's facilities in New Jersey and Puerto Rico, and the resulting deterioration in the company's relationship with the FDA. Given the limited nature of this motion, plaintiffs will not detail that evidence here. Nevertheless, the record makes clear that before and during the Class Period, the FDA's dissatisfaction with Schering-Plough's state of compliance was readily apparent as a result of repeated, failed inspections, Warning Letters, product recalls of life-saving medicine and meetings with senior FDA officials. Beginning in 1998 and continuing through the Class Period and thereafter, Schering-Plough's facilities in New Jersey and Puerto Rico underwent a series of FDA inspections that resulted in numerous citations of GMP violations. The inspections also gave rise to four FDA Warning Letters issued to the company's New Jersey and Puerto Rico facilities between 1998-2000. [Hoffman Decl., Exs. 6-7, 9-10].

If an FDA inspection reveals significant violations of GMPs, the firm will typically be issued a form known as an FDA-483 ("Form 483") that lists the objectionable conditions. The failure of a firm to adequately address a Form 483 observation may result in the issuance of a "Warning Letter" to the firm's top management. Warning Letters are normally issued when a GMP violation is such that the failure to undertake prompt and adequate corrections may be expected to result in an enforcement action.

In 1998, the FDA issued Warning Letters to Schering-Plough's New Jersey and Las Piedras facilities. [Hoffman Decl., Exs. 6-7]. (A third Warning Letter was also issued in 1998 to a company facility in Brinny, Ireland that manufactured "biologic" products. [Hoffman Decl, Ex. 8].) The New Jersey facility received another Warning Letter in 1999. [Hoffman Decl., Ex. 9]. The Company's Manati facility received a Warning Letter in 2000. [Hoffman Decl., Ex. 10]. The Las Piedras facility received an "Untitled Letter" in 2000 that, while not specifically designated as a Warning Letter, contained language similar to that typically found in Warning Letters, including the admonition that "[f]ailure to promptly correct these deviations may result in regulatory action without further notice," including "seizure and/or injunction." [Hoffman Decl., Ex. 11].

In the span of a one year period from June 1999-June 2000, Schering-Plough met three times with high level FDA officials and was told on each occasion that

the Agency had a "crisis of confidence" in the company's ability to comply with GMPs and manufacture products according to approved processes. [*See* Hoffman Decl., Ex. 12, Ex. 13 at SPSSI 087695, Ex. 14 at SGPCMO 13221, Ex. 15 at SPLPO 018971, Ex. 16 at SPSSI 100425, Ex. 17 at SPSSI 127189]. At one such meeting, in October 1999, a top FDA compliance official told Schering-Plough that the company's overall state of compliance was "questionable" and the director of the FDA's Center for Drug Evaluation and Research issued a pointed warning "that the Agency's next enforcement action would not be a Warning letter." [Hoffman Decl., Ex. 14 at SGPCMO 13223, Ex. 15 at SPLPO 018972]. One month into the Class Period, in June 2000, the FDA convened a meeting with the company "in lieu of" issuing another Warning Letter and Schering-Plough was told that the Agency's concerns were "at a higher level" than a Warning Letter. [Hoffman Decl., Ex. 16 at SPSSI 100424, Ex. 17 at SPSSI 127185].

The FDA was not the only party to forcefully express concerns with Schering-Plough's state of compliance. The company's own GMP compliance consultant, AAC Consulting Group, also expressed to the company in no uncertain terms that an FDA enforcement action was looming given the Warning Letters that had been issued, the recalls of asthma aerosol inhalers undertaken as a result of manufacturing canisters that failed to contain any active ingredient, and the persistence of "broken" quality systems and "out of control" situations observed by

AAC's auditors. In January 2000, AAC's president told Schering-Plough that its plans for redressing the compliance deficiencies were inadequate, that the FDA was likely considering the imposition of a consent decree and that the company should "beg for mercy" from the Agency. [Hoffman Decl., Ex. 19 at AAC 39540-41]. Just days before the beginning of the Class Period, on April 27, 2000, AAC provided Schering-Plough with a report of an in-depth audit that it conducted of the Kenilworth manufacturing facility. [Hoffman Decl., Ex. 22]. The report identified "serious cGMP systems failures and compliance lapses" and bluntly warned that "that the facilities and corporation are at serious risk of a significant FDA regulatory action." [*Id.* at SPSSI 061993].

Schering-Plough management recognized that the company faced an appreciable risk that the FDA would seek to impose a consent decree. In a speech to company employees after the October 1999 FDA meeting, defendant Cesan acknowledged that ". . . should we not raise the confidence of the FDA, I think that there is a possibility that the next step can be a consent decree. That is a serious matter." [Hoffman Decl., Ex. 18 at SPSSI 112011]. In January 2000, defendant Kogan sent a letter to Schering-Plough's board of directors to give them a "heads-up" on an article that the *Wall Street Journal* was preparing to publish about the company. Kogan told the board that "[i]t is not yet clear whether the FDA will take any enforcement or other action." [Hoffman Decl., Ex. 20]. Yet when the

article appeared days later, Cesan was quoted as stating, "We have resolved all the issues that were issues addressed by the FDA. We do not expect to have any problems with the FDA going forward." [Hoffman Decl., Ex. 21].

In the wake of the April 2000 AAC audit report and the June 2000 FDA meeting, Schering-Plough embarked on a crash 90-day remediation effort in an attempt to ready itself for an anticipated re-inspection by the FDA. [*See* Hoffman Decl., Exs. 23, 24]. The effort failed. When FDA investigators returned to the New Jersey facility, they were highly critical of the company's 90-day project and, in January 2001, issued a stinging rebuke of the facility's quality control unit: "The Quality Control Unit failed to assure that drug products were manufactured in compliance with cGMPs and therefore have the safety, quality, and purity that they purport, or are represented to possess." [Hoffman Decl., Ex. 25 at SPSSI 189427]. At the same time, the FDA withheld approval of the Clarinex NDA as a result of, among other things, the New Jersey inspection and outstanding compliance issues at the company's Las Piedras facility. [Hoffman Decl., Ex. 26].

B. Defendants Kelly and Wyszomierski Failed to Assure the Truthfulness and Accuracy of Schering-Plough's SEC Filings

Although Schering-Plough received three FDA Warning Letters in 1998 and another Warning Letter in July 1999, the company's 1999 10-K, filed on March 2, 2000, was the first time that the company's SEC filings contained *any* discussion of Warning Letters or good manufacturing practices. While compliance problems

and concerns for a consent decree swirled about the company, defendants Kelly and Wyszomierski remained largely oblivious of them. As such, they had no personal knowledge of the facts underlying the disclosures in the 1999 10-K that they signed. Nor did Kelly acquire such knowledge by the time he signed the 2000 Forms 10-Q filed during the Class Period.

Kelly, for example, testified that he never saw or heard any discussion of the Warning Letters issued to Schering Plough by the FDA. [Hoffman Decl., Ex. 29 at 58:22-59:17, 75:4-24, 138:18-139:14]. He did not know about the significant "crisis of confidence" meetings with the FDA, nor did he know that one month into the Class Period, the Agency had convened a meeting "in lieu of issuing a warning letter." [*Id.* at 122:14-126:12, 147:5-148:13]. He neither attended nor heard any discussion of the November 1999 speech of defendant Cesan to company employees that raised the possibility of an FDA consent decree. [*Id.* at 126:13-127:3]. He was unaware of the activities of AAC, including the AAC audit report issued just days before the beginning of the Class Period warning that the "facilities and corporation are at serious risk of a significant FDA regulatory action." [*Id.* at 62:10-16, 139:23-142:13].

Wyszomierski was similarly unaware of the underlying facts pertaining to the disclosures of FDA compliance matters in Schering-Plough's SEC filings. For example, he did not know that the company had received three FDA Warning

Letters during 1998 before he signed the Company's 1998 Form 10-K. [Hoffman Decl., Ex. 30 at 69:22-70:9]. He did not recall seeing or having discussions about other FDA Warning Letters issued in 1999 and 2000. [*Id.* at 74:17-75:11, 175:25-176:25]. He, too, was unaware of significant meetings between the Company and the FDA. [*Id.* at 74:17-75:19, 111:6-114:11, 184:10-185:10]. He neither saw nor discussed AAC's audit report and "didn't have a full appreciation" of the scope of the deficiencies identified by AAC. [*Id.* at 179:12-181:23]. He does not recall ever discussing manufacturing or quality issues with any of the senior management of those organizations. [*Id.* at 36:13-37:12].

Even though they knew little about FDA regulatory matters, neither Kelly nor Wyszomierski did anything to verify the accuracy of disclosures that they signed. Instead, they relied on Schering-Plough's law department to draft these disclosures and to ensure that they were truthful, accurate and complete. [Hoffman Decl., Ex. 29 at 35:10-36:8, 67:2-69:25, 130:25-133:6, 134:18-136:1, 153:14-155:10, 203:7-19; Ex. 30 at 154:5-161:19, 174:4-175:13, 211:16-213:24, 218:21-220:16]. The disclosures at issue were initially drafted for inclusion in the 1999 10-K by William Silbey, Schering-Plough's associate general counsel and corporate secretary. In connection with his drafting of the "Government Regulation" and "Additional Factors" sections of the 1999 10-K, Silbey held discussions with other lawyers within Schering-Plough's law department and with

certain management of the company's manufacturing, quality assurance and quality control divisions. [*See* Hoffman Decl., Ex. 31 at 109:10-110:2, 145:11-147:9]. On January 26, 2000, Silbey sent Joseph Connors, Schering-Plough's general counsel, the draft disclosure language, together with a memorandum discussing them. [*Id.* at 139:15–140:12]. Silbey's initial draft was then modified, based on input from Connors. [*Id.* at 145:11-148:8].

In February 2000, drafts of the 1999 10-K and the financial section of the 1999 Annual Report (included as a exhibit to the 1999 10-K) were forwarded to the board of directors for review and approval. [Hoffman Decl., Exs. 32, 33]. In regard to the challenged disclosures, the drafts forwarded to the board were identical to the language contained in the 1999 10-K that was ultimately filed by the company on March 2, 2000. Unlike the 1999 10-K, there is no evidence in the record indicating that the 2000 Forms 10-Q were reviewed or approved by the board. Approval for filing the Forms 10-Q came from Kelly and Wyszomierski, among others. [Hoffman Decl., Ex. 29 at 81:18-82:14; Ex. 30 at 56:10-58:9].

Kelly and Wyszomierski had a general understanding that Silbey would consult with others in preparing the challenged disclosures, but no knowledge of what Silbey actually did. They did not know the individuals with whom Silbey consulted, what documents he reviewed or the substance of any information he acquired. In short, they left it entirely to Schering-Plough's law department to

determine the nature and extent of any disclosures concerning relations with the FDA and GMP compliance matters, and took no steps whatsoever to verify the information contained in the SEC filings they signed.

Both Silbey's draft disclosure language and his January 26, 2000 memorandum were withheld from production by defendants on a claim of attorney-client privilege. Plaintiffs sought to compel production of these documents, contending that the privilege was waived because defendants Kelly and Wyszomierski have asserted an affirmative defense that their statements were made in "good faith" and there is no factual basis for their assertion of good faith other than reliance on counsel. In opposing the application, defendants expressly disclaimed any assertion of an advice of counsel defense and contended that Kelly and Wyszomierski had merely relied on company procedures that were used to prepare the textual portions of the SEC filings. Magistrate Judge Falk denied plaintiffs' application, ruling that a waiver of the privilege did not occur because the defendants did not invoke and cite legal advice as the reason why they did not act with the required state of mind. [*See* Hoffman Decl., Ex. 34].

III. ARGUMENT

To prevail on their claims under Section 10(b) of the Exchange Act, plaintiffs must prove: (i) that defendants made a misrepresentation or omission; (ii) of material fact; (iii) that defendants acted with knowledge or recklessness (i.e.,

scienter); (iv) that plaintiffs reasonably relied on the misrepresentation or omission; and (v) consequently suffered damage. *In re Advanta Corp. Sec. Litig.*, 180 F.3d at 537. By this motion, plaintiffs seek a summary adjudication of the scienter of defendants Kelly and Wyszomierski. While plaintiffs believe that the evidence establishing each of the elements of their securities fraud claim is overwhelming, they recognize that issues pertaining to matters such as materiality and loss causation are highly fact intensive and are generally regarded as inappropriate for summary judgment. *See, e.g., Shapiro v. UJB Financial Corp.*, 964 F. 2d 272, 280 n. 11(3d Cir. 1992); *In re Loewen Group Sec. Litig.*, 395 F. Supp. 2d 211, 216-218 (E.D. Pa. 2005). However, the evidence is incontrovertible that these defendants made statements without any understanding of whether there was a genuine factual basis for making them. Plaintiffs submit that such conduct constitutes recklessness as a matter of law, and that if the jury finds that defendants' statements were materially misleading, it should be instructed that the statements were made with scienter.

A. Standards for Partial Summary Adjudication

Summary judgment is appropriate where the moving party establishes that "there is no genuine issue as to any material fact and that [it] is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). A factual dispute is genuine if a reasonable jury could return a verdict for the non-movant and it is material if,

under the substantive law, it would affect the outcome of the suit. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The central issue of the motion, therefore, is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Id.* at 251-52.

Summary judgment may be granted as to particular issues within a claim. *See* Fed. R. Civ. P. 56(a) (summary judgment may be granted as to "all or any part" of a claim). A motion for partial summary judgment has been recognized as a "useful tool" for narrowing the issues for trial. *McDonnell v. Cardiothoracic & Vascular Surgical Assoc., Inc.*, 2004 WL 1234138 at *1 (S.D. Ohio 2004). As such, courts within this circuit and elsewhere have considered motions that seek an adjudication of particular elements of a claim. *See Nutrition Management v. Harborside Healthcare Corp.*, 2004 WL 764809 at *3 (E.D. Pa. 2004) (considering motion that "does not seek summary judgment with respect to any single claim"); *Rhythm & Hues, Inc. v. The Terminal Marketing Co.*, 2004 WL 941908 at *8 n. 7 (S.D.N.Y. 2004) ("it is now well-established that a court may 'grant' partial summary 'judgment' that establishes the existence or non-existence of certain facts"); *Gulfstream III Assoc., Inc. v. Gulfstream Aerospace Corp.*, 1990 WL 127124 at * 3 (D. N.J. 1990) (considering plaintiffs' motion as to two elements of an antitrust claim); *Florham Park Chevron, Inc. v. Chevron U.S.A.*,

Inc., 1987 WL 19492 at * 4 (D.N.J. 1987) (finding pursuant to Rule 56(d) that certain facts exist without substantial controversy).

B. Plaintiffs Are Entitled to Partial Summary Judgment Against Kelly and Wyszomierski on the Scienter Element of Their Claim

In order to prevail on their Rule 10b-5 claim, plaintiffs must prove, *inter alia*, that materially misleading statements were made with scienter, "a mental state embracing intent to deceive, manipulate or defraud." *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 (1976). Scienter may be proven by establishing facts that constitute circumstantial evidence of either reckless or conscious behavior. *In re Advanta Corp. Sec. Litig.*, 180 F.3d at 534-35. "A reckless statement is one 'involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers . . . that is either known to the defendant or is so obvious that the actor must have been aware of it.'" *Id.* at 535. Imposing liability for reckless conduct "promotes the policy objectives of discouraging deliberate ignorance." *Id.* Thus, "'ignorance provides no defense to recklessness where a reasonable investigation would have revealed the truth.'" *SEC v. Infinity Group Co.*, 212 F.3d 180, 193 (3d Cir. 2000). *See also Herskowitz v. Nutri/System*, 857 F.2d 179, 184 (3d Cir. 1988) (a representation "will be deemed untrue for purposes of the federal securities laws if it is issued without reasonable genuine belief or if it has no basis"). Recklessness may be inferred where defendants "had access to

information suggesting their public statements were not accurate" or where they "failed to check information they had a duty to monitor." *In re U.S. Interactive Sec. Litig.*, 2002 WL 1971252 at * 13 (E.D. Pa. 2002). *See also In re Campbell Soup Co. Sec. Litig.*, 145 F. Supp. 2d 574, 599 (D.N.J. 2001).

Kelly signed each of the three 2000 Forms 10-Q filed by Schering-Plough during the Class Period. Wyszomierski signed the company's 1999 Form 10-K, portions of which were incorporated by reference in the 2000 Forms 10-Q and which are alleged by plaintiffs as false and misleading. As such, they made statements to the investing public that subject them to liability under Section 10(b). *Howard v. Everex Sys.*, 228 F. 3d 1057, 1061 (9th Cir. 2000); *In re Reliance Sec. Litig.*, 135 F. Supp. 2d 480, 505 (D. Del. 2001). The fact that neither Kelly nor Wyszomierski participated in drafting the challenged disclosures does not relieve them of liability. In *Reliance*, for example, the court denied the outside director defendants' motion for summary judgment despite the fact that the directors had not prepared the allegedly misleading filings they signed. The *Reliance* court adopted the reasoning of *Howard v. Everex*, observing that:

> In *Howard*, the Ninth Circuit found that an officer who signs an SEC filing makes a statement under Section 10(b), even if the officer did not participate in the drafting of the statement. The court reasoned that corporate officers ought to be held responsible for the statements in the documents and that "by placing responsibility in corporate officers to ensure the validity of corporate filings, investors are further protected from misleading information." The court further stated, "key corporate officers should not be allowed to make important false

> . . . statements knowingly or recklessly, yet still shield themselves from liability to investors simply by failing to be involved in the preparation of those statements."

135 F. Supp. 2d at 503-04.

Here, there is no dispute that Kelly and Wyszomierski were unfamiliar with the most basic facts relevant to the challenged disclosures, including the FDA Warning Letters, key FDA meetings and the activities of AAC. There is also no dispute that they relied entirely on Schering-Plough's law department to draft each of the challenged disclosures and took no action on their own to verify the truthfulness and accuracy of the disclosures. Significantly, as discussed above, defendants have expressly disclaimed any reliance on advice of counsel in signing the challenged disclosures. Instead, Kelly and Wyszomierski assert that they relied in good faith on established company procedures that were used to prepare the SEC filings. Insofar as the challenged disclosures are concerned, however, the procedures undertaken to draft the 1999 10-K and 2000 Forms 10-Q were the exclusive province of Schering-Plough's law department. While these defendants may have had a vague understanding that the law department would draft language based on discussions that the lawyers had with the management of other parts of the company, they had no knowledge of the information obtained through any such discussions, whether any such information provided an adequate basis for the

disclosures or why the disclosures included certain facts and omitted others. [*See, e.g.*, Hoffman Decl., Ex. 29 at 103:7-105:21, 111:12-113:3, 132:16-134:10].

The record establishes, therefore, that Kelly and Wyszomierski effectively abdicated to the company's lawyers their responsibility for ensuring the truthfulness and accuracy of Schering-Plough's disclosures. Because they had no genuine basis for believing that the challenged disclosures were truthful and accurate, defendants' conduct in signing the company's SEC filings was reckless. *See SEC v. Infinity Group*, 212 F.3d at 193 (3d Cir. 2000) ("'ignorance provides no defense to recklessness where a reasonable investigation would have revealed the truth to the defendant'"); *Advanta*, 180 F.3d at 535 (recklessness standard "promotes the policy objectives of discouraging deliberate ignorance"); *Herskowitz v. Nutri-System*, 857 F.2d at 184 (imposing liability for representations made "without reasonable genuine belief"). Accordingly, to the extent that the challenged disclosures are found by the jury to have been materially false or misleading, the Court should instruct that defendants Kelly and Wyszomierski acted in reckless disregard of the truth.

IV. CONCLUSION

For all of the foregoing reasons, plaintiffs respectfully request that the Court grant their motion for partial summary judgment on the "scienter" element of their

claim under Section 10(b) of the Exchange Act against defendants Kelly and Wyszomierski.

Dated: December 12, 2007

Respectfully submitted,

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